A 2 Cont

45 (New). A method of claim 44 wherein said antibodies are monclonal antibodies.

REMARKS

Status of the claims

Claims 1-33 are pending in the application.

Claims 1-24 and 33 have been withdrawn from consideration/

Claims 25-32 have been rejected.

By way of this amendment, claims 1-24 and 33 have been canceled, claims 25-31 have been amended and new claims 34-45 have been added.

Upon entry of this amendment, claims 25-32 and 34-45 will be pending.

Summary of the Amendment

Claims 1-24 and 33 have been canceled as being directed at non-elected inventions. The subject matter in claims 1-24 and 33 is expressly reserved.

Claims 25-31 have been amended to more clearly define embodiments of the invention. Claism 25 and 29 more clearly refer to diagnosis of cancer in patients who are suspected of having such cancer. The steps of the method are clearly set forth in the claims as amended. Claim language is amended to make the claim more clear and consistent with other claims. Support for the amendment is found throughout the specification. No new matter has been

added.

Claims 26 and 27 and claims 30 and 31 have been amended to make them more clear and consistent with claims 25 and 29, respectively. Support for the amendment is found throughout the specification. No new matter has been added.

Claim 28 has been amended to correct its dependency. Support for the amendment is found throughout the specification. No new matter has been added.

New claims 34 and 35 are dependent on claims 28 and 31, respectively, and have been added to specifically recite that the antibodies used are monoclonal antibodies. Support for the amendment is found throughout the specification. No new matter has been added.

New claims 36-45 correspond to claims 25-28, 34, 29-32 and 35, respectively, except new claims 36-45 refer to specific embodiments in which the individual has already undergone cancer treatment and the method is performed to determine if the individual still has cancer, either due to relapse or incomplete elimination following treatment. Support for the amendment is found throughout the specification. No new matter has been added.

Rejection under 35 U.S.C. §112, second paragraph

Claims 25-27 and 29-31 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted that claims 25 and 29 are unclear for failing to

set forth steps needed for detection.

Claims 25 and 29 have been amended to more clearly set forth the steps required to perform the claimed methods. To comply with the second paragraph of 35 U.S.C. §112, the claims must clearly set froth the metes and bounds of the claims. As amended, those skilled in the art woudl readily identify the subject matter embraced by the claims as distinguished fromsubject matter not covered by the claims. The claims as amended are clear and definite and recite sufficient details to define the invention.

Applicants respectfully request that the rejection of claims 25-27 and 29-31 under 35 USC 112, second paragraph be withdrawn.

Rejection under 35 U.S.C. §102

Claims 25, 28, 29 and 32 have been rejected under 35 U.S.C. §102(b) as being anticipated by Silberg. It is asserted that Silberg teaches detection of CDX1 in adenocarcinomas of the stoch ands esophagus using antibodies specific for CDX1.

In order to anticipate a claim, every element of the claim must be set forth in the reference, either expressly or inherently. Claims 25, 28, 29 and 32 are not anticipated by Silberg. Nothing in Silberg disclosed the elements in the claims as amended which recite that the individual is suspected of having cancer and that the claimed method can be used to confirm the suspicion and diagnose the individual as having cancer.

Applicants respectfully request that the rejection of claims 25, 28, 29 and 32 under 35 USC 102 be withdrawn.

Rejection under 35 U.S.C. §103

Claims 25, 28, 29 and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Silberg in view of Wu.

It is asserted that Silberg teaches detection of CDX1 in adenocarcinomas of the stomach and esophagus using antibodies specific for CDX1.

It is asserted that Wu teaches using PRC to identify SI mRNA using PCR in specimens having Barrett's syndrome and esophageal cancer.

It is asserted that it would be prima facie obvious to those skilled in the art to combine the teachings of Silberg and Wu in order to use PCR to identity CDX1 mRNA in specimens in order to diagnose stomach and esophageal cancer. It is asserted that one would be motivated to combine the teachings because PCR provides a highly specific assay and because CDX1 binds to the SI promoter.

Claims 25-27 and 29-31 are not obvious in view of Silberg and Wu. Nothing in the combination of Silberg and Wu teaches or suggest the subject matter of the claims as amended which recite that the individual is suspected of having cancer and that the claimed method can be used to confirm the suspicion and diagnose the individual as having cancer. The combined

teachings of the references to not render the invention as claimed obvious.

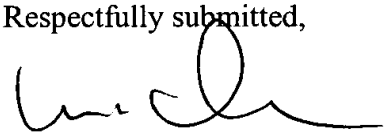
Applicants respectfully request that the rejection of claims 25-27 and 29-31 under 35 USC 103 be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Conclusion

Claims 25-31 as amended and new claims 34-45 are in condition for allowance. A notice of allowance is earnestly solicited.

Respectfully submitted,



Mark DeLuca
Registration No. 33,229

Date: Sept 12 2002

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-24 and 33 have been canceled without prejudice, claims 34-45 have been added and claims 25-31 have been amended as follows.

25 (Amended). A method of diagnosing stomach cancer in an individual who is suspected of having [has] stomach cancer comprising the steps of: a) identifying the individual as being suspected of having stomach cancer; b) obtaining a sample of stomach tissue from said individual; c) [examining a sample of stomach tissue to detect] detecting the presence of CDX1 gene transcript or translation product in said sample of stomach tissue; wherein the presence of CDX1 gene transcript or translation product in said sample of [a] stomach tissue [sample] indicates that the individual has stomach cancer.

26 (Amended). The method of claim 25 comprising the step [steps] of [examining] detecting the presence of CDX1 transcript in said sample of stomach tissue. [to determine whether CDX1 gene transcription product is present in said sample.]

27 (Amended). The method of claim 26 wherein the presence of CDX1 gene [transcription product] transcript is detected using [determined by] polymerase chain reaction wherein said

sample is contacted with primers that selectively amplify CDX1 gene transcript or cDNA generated therefrom.

28 (Amended). The method of claim 25 [26] wherein the presence of CDX1 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX1 gene translation product.

29 (Amended). A method of diagnosing esophageal cancer in an individual who is suspected of having [has] esophageal cancer comprising the steps of: a) identifying the individual as being suspected of having esophageal cancer; b) obtaining a sample of esophageal tissue from said individual; c) [examining a sample of esophagus tissue to detect] detecting the presence of CDX1 gene transcript or translation product in said sample of esophageal tissue; wherein the presence of CDX1 gene transcript or translation product in said sample of [an] esophageal tissue [sample] indicates that the individual has esophageal cancer.

30 (Amended). The method of claim 29 comprising the step [steps] of [examining] detecting the presence of CDX1 transcript in said sample of esophageal tissue. [to determine whether CDX1 gene transcription product is present in said sample.]

31 (Amended). The method of claim 30 wherein the presence of CDX1 gene [transcription product] transcript is detected using [determined by] polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX1 gene transcript or cDNA generated therefrom.

34 (New). A method of claim 28 wherein said antibodies are monclonal antibodies.

35 (New). A method of claim 32 wherein said antibodies are monclonal antibodies.

36 (New). A method of determining if an individual who has been treated for stomach cancer continues to have stomach cancer or has had a relapse comprising the steps of: a) identifying the individual who has been treated for stomach cancer; b) obtaining a sample of stomach tissue from said individual; c) detecting the presence of CDX1 gene transcript or translation product in said sample of stomach tissue; wherein the presence of CDX1 gene transcript or translation product in said sample of stomach tissue indicates that the individual continues to have stomach cancer or has had a relapse.

37 (New). The method of claim 36 comprising the step of detecting the presence of CDX1

transcript in said sample of stomach tissue.

38 (New). The method of claim 37 wherein the presence of CDX1 gene transcript is detected using polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX1 gene transcript or cDNA generated therefrom.

39 (New). The method of claim 36 wherein the presence of CDX1 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX1 gene translation product.

40 (New). A method of claim 39 wherein said antibodies are monclonal antibodies.

41 (New). A method of determining if an individual who has been treated for esophageal cancer continues to have esophageal cancer or has had a relapse comprising the steps of: a) identifying the individual as being suspected of having esophageal cancer; b) obtaining a sample of esophageal tissue; c) detecting the presence of CDX1 gene transcript or translation product in said sample of esophageal tissue; wherein the presence of CDX1 gene transcript or translation product in said sample of esophageal tissue indicates that the individual continues to have stomach cancer or has had a relapse.

42 (New). The method of claim 41 comprising the step of detecting the presence of CDX1 transcript in said sample of esophageal tissue.

43 (New). The method of claim 42 wherein the presence of CDX1 gene transcript is detected using polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX1 gene transcript or cDNA generated therefrom.

44 (New). The method of claim 41 wherein the presence of CDX1 gene translation product is determined by immunoassay wherein said sample is contacted with antibodies that specifically bind to CDX1 gene translation product.

45 (New). A method of claim 44 wherein said antibodies are monoclonal antibodies.